



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,016	07/10/2001	David L. Thompson	P-9153.05	8319
27581	7590	09/10/2004	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			JASMIN, LYNDA C	
			ART UNIT	PAPER NUMBER
			3627	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/902,016	THOMPSON, DAVID L.	
	Examiner Lynda Jasmin	Art Unit 3627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 May 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3 and 5-32 is/are rejected.
- 7) Claim(s) 4 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on May 26, 2004 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of any patent granted on Application No. 09/775,281 filed February 1, 2001 and Application No. 09/775,262 filed February 1, 2001 has been reviewed and is NOT accepted.

The terminal disclaimer does not comply with 37 CFR 1.321(b) and/or (c) because: on 2nd page, 1st sentence, the word "application" should be pluralized.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

Art Unit: 3627

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 17-20, 25, 26, 30-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7-9 of copending Application No. 09/775,281. Although the conflicting claims are not identical, they are not patentably distinct from each other because having an inventory and production control system synchronous with various phases of product manufacturing standard, customized and newly approved, modified/redesigned devices and utilizing an inventory management system to select a user-specific configuration based on customized order achieved the same end result of utilizing an information network in data communication with manufacturing.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1-3, 5-21, 23-26, 30-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7-9 of copending Application No. 09/775,262. Although the conflicting claims are not identical, they are not patentably distinct from each other because having a device manufacturing and supply information management for customized features with customized data set and utilizing an inventory management system to select a patient-

Art Unit: 3627

specific configuration based on customized order achieved the same end result of utilizing an information network to received patient specific data for manufacturing.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At line 1, the recitation "the software means" lacks proper antecedent basis. Further, the word "means" is preceded by the word(s) "software" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Linberg et al. (6,497,655 B1).

Linberg discloses a system to control the configuration of an implantable medical device (IMD) [(Fig. 4: IMD (10)] including:

a Web-enabled information network [col. 11, line 23: the communication between programmer (20), and expert data center (62) is web-enabled], a storage device capable of receiving information from the information network to receive patient-specific data (Fig. 4: each of the modules (100, 102, 104) receive and store patient-specific data (e.g., Fig. 6: step 160)], and a processing circuit coupled to the storage device to select components to be integrated in the IMD based on the patient-specific data (col. 20, lines 19-22: PPM makes recommendation for upgrade/modifications to be integrated into the IMD). Linberg further discloses software components loaded into the storage device and selected by the processing circuit as one or more of the components selected for use in the configuration of the IMD (Fig. 5). The software means is selected from the group consisting of software and/or firmware-implemented digital signal processing processes (via digital circuit), filters (via wireless communications system through which data and information is transmitted between programmer 20 and data center 62), and signal differentiation processes (via analyzer 106). The processing circuit includes

Art Unit: 3627

parameter selection means for selecting predetermined parameters to be downloaded into the IMD (col. 9, lines 19-44).

9. Claims 1-3 and 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt et al. (5,725,559).

Alt et al. discloses a system to control the configuration of an implantable medical device (IMD) (Fig. 4C: device 10 is a programmable implant) including: a Web-enabled information network (col. 4, line 55: the communication between programmer (40) and manufacturer is via Internet (i.e., web-enable)), a storage device capable of receiving information from the information network (col. 9, line 11 through col. 10, line 9; discloses programmer (40) to be a computer therefore, it must necessarily store the information in order to perform the stated functions) to receive patient-specific data (col. 4, lines 50-52: the upgrade data received from the manufacturer via the internet is “patient-specific” in that it requires a specific device serial number, i.e., a unique ID associated with a specific device implanted in a specific patient), and a processing circuit coupled to the storage device to select components to be integrated in the IMD based on the patient-specific data (Fig. 4C; col. 9, lines 46-53: the patient specific upgrade data received is used to determine which functions to enable/disable in the implant device (10)).

Alt further discloses software components loaded into the storage device (Fig. 3) and selected by the processing circuit as one or more of the components selected for use in the configuration of the IMD (col. 8, lines 15-34). A manufacturing system coupled to receive Information Indicative of the selected components, wherein the received Information is used during manufacture of the IMD (via col. 4, lines 23-48). Alt

Art Unit: 3627

further discloses a testing system to receive information indicative of the selected component, wherein the received information (such as signals generated from the patient-specific data) is used in testing a manufactured IMD (col. 8, line 64 - col. 9, line 10). The processing circuit includes means for selecting hardware components to be used during manufacture of the IMD based on the patient-specific data (col. 4, lines 4-22).

10. Claims 12-23 and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al. (5,725,559), in view of Colligan et al. (6,298,443).

Alt et al. discloses all the elements of the claimed invention a medical device manufacturing as disclosed in paragraph 9 above, and further discloses customized order including physiological data and modifying a selected software algorithm based on the physiological data [via sensor means (12): col. 6, lines 36-55]. However, Alt fails to explicitly disclose monitoring inventory levels and transferring customized orders to for the IMD from a remote site to the inventory management.

Colligan et al. discloses the concept of maintaining and inventory via an asset tag (col. 11, lines 24 and 25). Colligan et al. further discloses the concept of having a build-to-order custom-programmed CD ROM that is configured for a specified individual computer system (with Service Tag number of the specified computer system) and constraint to be downloaded to and operable on only the specified individual computer system. Colligan et al. also discloses a software transport package manufacturing process (300) to retrieve customer order record by part number and a shipping method.

Art Unit: 3627

From this teaching of Colligan et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modify the upgradable implanted medical device of Alt et al. to include the customized order fulfillment taught by Colligan et al. in order to fit customer's specific needs.

Allowable Subject Matter

11. Claim 4 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

12. Applicant's arguments with respect to claims 1-32 have been considered but are moot in view of the new ground(s) of rejection.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda Jasmin whose telephone number is (703) 305-0465. The examiner can normally be reached on Monday- Friday (8:00-5:30) alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert P Olszewski can be reached on (703) 308-5183. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3627

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lynda Jasmin
Primary Examiner
Art Unit 3627

Ij